Prevention of Salmonella Enteritidis in Shell Eggs During Production---Recordkeeping and Registration Provisions

Summary of Comments

In the proposed rule, FDA proposed certain recordkeeping requirements and solicited comments on whether additional recordkeeping measures should be required for a comprehensive SE prevention plan, and whether a written SE prevention plan should be required. Several comments supported the proposed recordkeeping requirements but did not comment on expanding them; one comment stated that there is no need for FDA to expand its recordkeeping requirements beyond those proposed. In addition, several comments supported expanding the proposed recordkeeping requirements to include a written SE prevention plan and records for compliance with SE prevention measures. Several comments noted that such records have been very useful in conducting inspections of facilities to determine compliance with the egg quality assurance program requirements and for identifying problems in the producer's SE prevention plan when a test is positive. Another comment stated that records documenting compliance with all aspects of the SE prevention plan will be essential for a producer to determine if their plan is effective and in making adjustments to improve their plan. One comment opposed the requirement of a written SE prevention plan, stating that while a written plan would undoubtedly be an important management tool, and indeed many operations have such a plan, it is not necessary for FDA to mandate such a document. The comment stated FDA should not place undue emphasis on paperwork, as opposed to actual results. The comment suggested that FDA work with interested parties to develop a model SE prevention plan that could be provided to egg producers for their use.

Two comments stated that FDA should require purchasers of diverted eggs (e.g., egg breaking facilities, shell pasteurization facilities, hard-cooked operations, or other facilities where the eggs could be treated) to maintain records indicating that the diverted eggs have been treated. These comments, submitted by an agricultural department and poultry and livestock commission of two major shell egg producing states, argued that without records there would be no ability to ensure the purchaser would treat the eggs and not simply divert them back to the table egg market.

One comment commended FDA's statement that "we intend to consider records that come into our possession under this rule as generally meeting the definition of a trade secret or commercial confidential materials" (69 FR 56824 at 56841). However, the comment requested that FDA identify in the final rule what information will be considered confidential commercial information (CCI) or a trade secret, and under what legal authority FDA will defend this designation against any legal challenges.

One comment encouraged FDA to incorporate an automated recordkeeping requirement into the proposed rule. The comment stated that an automated system would enhance and support the recordkeeping requirements outlined in the proposed rule. The comment argued that such a system could provide farm-specific data, and an efficient, cost-effective way to research compliance. The comment stated that an automated

system would greatly reduce the recordkeeping burden placed upon egg producers as well as the time, frequency, and cost associated with FDA inspections.

In the proposed rule (69 FR 56841 at 56841 through 56842), FDA solicited comments about whether we should require that shell egg producers register with FDA. Several comments supported requiring registrations by egg producers covered by the SE prevention measures. These comments stated that registration of all producers covered by any of the SE prevention measures would be the most efficient method of obtaining the information needed to conduct annual inspections and allocate resources.

Further, several comments stated that such a requirement should be consistent with the program developed under the agency's bioterrorism regulations. The comments further stated that by identifying each farm's location and size, a registration requirement would enable more efficient inspection, as well as better management and oversight of a shell egg recall.

One comment stated that, to create a level playing field across the United States, registering all producers is necessary and that FDA may be able to cooperate with USDA/APHIS, which is presently developing a premises identification program for all animal premises in the United States.

One comment objected to requiring producers who pack eggs to register, stating that every producer with packing facilities is registered with the FDA under the registration rule and should not be required to register a second time. The comment agreed that producers that do not pack eggs, but sell eggs that will ultimately go into the table egg market, should be registered so that FDA can ensure these firms are following the on-farm production and testing requirements of the SE rule.

One comment objected to the proposed registration requirement as an unnecessary burden and an unreasonable invasion of privacy. The comment argued that FDA only should check for compliance. The comment further argued that "unexpected visits are not appropriate as a respect for other people and the reality is that no one can hide what you want to see in 24 hours." The comment further argued that registration will result in a loss of privacy for the producer and is unnecessary for the success of the program.

One comment expressed concern that information submitted to register facilities would be subject to the Federal Freedom of Information Act (5 U.S.C. 552), and that public release of this information could result in a decrease of security at the producer sites. The comment stated that FDA has other means at its disposal to learn the site information needed to administer this program and still respect the need for security at the producer sites.

Several comments suggested that FDA revise the proposed rule to make the environmental sampling plan flexible. In support of this suggestion, some comments stated that because the rule would cover very diverse egg laying facilities in the United States (e.g., free-range farms and confinement operations using cages or nesting boxes),

one single sampling plan would not be effective. One comment recommended a different sampling plan requirement for each operation type. The comment suggested that all confinement "barns" could be sampled under the same plan, and recommended that for such operations FDA require that a minimum of one manure drag sample be obtained from each bank of cages. The comment stated that more research is needed to determine the most appropriate sample sites for operations that are cage-free, pasture-raised, or free-range. Another comment noted that the sampling plan should also be flexible because of variations in operations within geographic areas and across geographic regions, for example, difference in manure collection/disposal systems.

One comment agreed with the sampling protocol established in § 118.6(c) for egg testing for SE, but stated that 24 hours is not a practical timeline to begin egg testing after a positive environment is found. The comment suggested that § 118.6(c) require egg producers to immediately notify the appropriate state agency of the positive environmental findings and that egg sampling commence within 2 weeks after the environmental test results are received. Another comment suggested that FDA revise the time period allowed between receiving a positive environmental sample and conducting the required egg testing from 24 to 72 hours to allow for weekends or holidays when laboratory facilities would most likely not be available to complete the tests. Several comments further argued that the 24-hour requirement for initiating egg testing is impossible, as even collecting the eggs within 24 hours might be difficult at times. In addition, the comments argued that to arrange testing for 1,000 eggs requires scheduling of several items, including people, labs, and media, and cannot be done in 24 hours.

One comment argued that a testing regulatory scheme would not be effective in preventing illnesses from SE. This comment stated that environmental and egg testing only indicates the status of the house at the time of the test.